Remarks

Rejection under 35 U.S.C. §112 first paragraph-written description

Claims 1-7 and 9 were rejected under 35 U.S.C. §112 first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection.

The Legal Standard

The general standard for the written description requirement is that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *See* M.P.E.P. §2163(I). Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*, citing *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998).

Written description is determined from the perspective of what the specification conveys to one of ordinary skill in the art. *In re GPAC Inc.*, 57 F.3d 1573, 1579, 35 U.S.P.Q.2d 1116,1121 (Fed. Cir. 1995); *Vas Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). The written description requirement does not require a description

of the complete structure of every species within a chemical genus. (*see Utter v. Hiraga*, 845 F.2d 993, 998, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988), stating "A specification may, within the meaning of 35 U.S.C. §112, para. 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses."). All that is required is that the specification provide sufficient description to reasonably convey to those skilled in the art that, as of the filing date sought, the inventor was in possession of the claimed invention. *Union Oil of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 U.S.P.Q.2d 1227, 1232 (Fed. Cir. 2000); *Vas Cath*, 935 F.2d at 1563-64. An applicant may show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Analysis

The claims define a drug formulation comprising a drug in an amount effective to provide relief from diseases and disorders of the breast in a pharmaceutically acceptable carrier for topical administration to the breast, wherein the drug is not a non-steroidal anti-inflammatory or analgesic. Claim 1 has been amended to specify that the drug is in a pharmaceutically acceptable carrier capable of delivering drug to the breast tissue and that the carrier contains a penetration enhancer to promote delivery of the drug across the stratum corneum. Support for this amendment can be found in the specification at least at page 6, lines 28-29, page 8, lines 3-5 and page 9, lines 1-2.

The Examiner alleged that the specification does not describe or exemplify any drug, much less any chemotherapeutic agent, hormones, hormone releasing agents, hormone analogs, antiestrogens, LHRH analogues and antiproliferative agents providing relief from diseases or disorders of the breast, and thus, does not provide a basis for one of skill in the art to envision the structural/functional characteristics of such a compound (Office action mailed on April 12, 2007, page 3). Applicants respectfully disagree with this allegation.

The specification at least from page 1, line 12, until page 2, line 16 describes disorders of the breast. The specification at least at page 7, lines 6-25 describes the drugs that can be incorporated into a formulation to treat diseases of the breast, and refers to the classification of pharmacologic agents and drugs in Goodman and Gilman, "The Pharmacological Basis of therapeutics", (9th Ed. McGraw-Hill Publishing Co.) (1996) ("Goodman and Gilman") (see attached index pages). Thus, drugs that can be incorporated in the claimed formulation are not only disclosed in the specification, they are also well known in the art.

The Examiner's attention is respectfully drawn to the fact that Applicants are not claiming drugs per se. The drugs in the claimed formulations are already known and well characterized in the art. The drugs that fall within the classification of "chemotherapeutic agent", "hormones", "hormone releasing agent", "hormone analogue", "antiestrogens", "LHRH analogues", and "anti-proliferative" agents are all known in the art (See for example, "Goodman and Gilman"). Furthermore, the specification from page 2, line 24 until page 4, line 27 provides examples of drugs that have been used to treat disorders of the breast. Therefore, one of ordinary skill in the art would know that applicants were in possession of the claimed formulations.

Therefore, claims 1-7 and 9 satisfy the written description requirement.

Rejection Under 35 U.S.C. §102

Claims 1, 2, 4-7 and 9 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,919,937 to Mauvais-Jarvis, *et al.* ("Jarvis"). Claims 1-4 and 6-9 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,993,856 to Ragavan, *et al.* ("Ragavan 1"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986); *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*:

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. There must be *no difference* between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (18 USPQ2d at 1010, emphasis added).

Further, a reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation (*see Id.*).

Analysis

Jarvis

Jarvis discloses an anti-estrogen drug which is derived from tamoxifen, which penetrates skin without any need for a penetration enhancer. The drug is administered percutaneously in a hydroalcoholic gel. Jarvis' drug is used for the treatment of mammary cancer (Jarvis, abstract). Jarvis does not disclose any penetration enhancers, even less a formulation that includes a penetration enhancer to promote the delivery of the drug across the stratum corneum into breast tissue in an amount effective to treat just breast tissue. Therefore, claims 1, 2, 4-7, and 9, as amended, are novel over Jarvis.

Ragavan 1

Ragaven 1 discloses formulations for topical or local delivery for administration of drugs to a region such as the reproductive organ and the surrounding environs (Ragavan 1, col. 7, lines 37-40). Although Ragavan 1 discloses including standard excipients in the formulation (*See* col. 3, line 24-37), Ragavan 1 is silent about including penetration enhancers in the formulation. The formulations disclosed in Ragavan 1 comprise an effective amount of a drug for treating a region. "Region" is defined in Ragavan 1 as reproductive organs and their surrounding environs, which include uterus, fallopian tube, peritoneal space, pelvic cul-de-sac, ovaries, perineum and the rectovaginal region (*See* Ragavan 1, at least at col. 7, lines 37-41). Thus, formulations disclosed in Ragavan 1 are meant for delivery across mucosal membranes, where drug is relatively contained with a reproductive blood barrier so that effective levels can be achieved throughout the region, but without systemic levels being achieved.

In contrast, the claimed formulations contain a drug in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue in combination with a penetration enhancer, which is used to promote delivery across the skin. to include any excipients that would be effective in functioning as a penetration enhancer. Therefore, claims 1-4 and 6-9, as amended, are novel over Ragavan 1.

Double Patenting Rejection

Claims 1-9 were rejected under the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 31-33 of Ragavan 1, claims 1-4 and 17 of U.S Patent No. 6,652,874 to Ragavan, *et al.* ("Ragavan 2") and claims 1-3 and 12 of U.S. Patent No. 6,416,778 to Ragavan, *et al.* ("Ragavan 3"). Applicants respectfully traverse this rejection to the extent that it pertains to the claims as amended.

Legal Standard

When determining whether the claims of an application define an invention that is an obvious variation of an invention defined in the claims of a patent, the claims of the application are compared with the claims in the patent, the disclosure in specification of the patent is not considered in the analysis (*see* MPEP §§ 800-822). The MPEP explains that "[a] double patenting rejection of the obviousness-type is 'analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. § 103' except that the patent principally underlying the double patenting rejection is not considered prior art." MPEP § 804(II)(B)(1), citing *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. 29 (CCPA 1967). Therefore, analysis employed in an obviousness-type double patenting rejection parallels the guidelines for a 35 U.S.C. § 103

obviousness determination. *Id.*, citing *In re Braat*, 937 F.2d 589, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985).

U.S. Patent No. 9,993,856 to Ragavan, et al. ("Ragavan 1")

Claims 1-9 were rejected under the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 31-33 of Ragavan 1. This rejection is improper based on a comparison of pending claims 1-9 with claims 1-15 and 31-33 of the Ragavan 1 as shown below.

Claims as Amended	**Claims of Ragavan 1**
1. A drug formulation comprising a drug in an amount effective to provide relief from diseases or disorders of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic. 2. The drug formulation of claim 1 wherein the drug is soluble in aqueous solutions. 3. The drug formulation of claim 1 wherein the drug is in the form of micro- or nano-particulates. 4. The drug formulation of claim 1 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam,	1. A micro- or nano-particulate drug formulation for local or regional topical administration of an effective amount to provide relief from symptoms associated with a disease or disorder in a region in patients in need thereof, wherein the effective amount is less than the effective amount when the drug is administered systemically. 2. The formulation of claim 1 wherein the region is the female reproductive organs. 3. The formulation of claim 2 wherein the patients have a disorder located in the reproductive organs. 4. The formulation of claim 1 wherein the formulation comprises drug particles. 5. The formulation of claim 3 wherein the drug is for treatment of endometriosis. 6. The formulation of claim 1 wherein the micro- or nano- particulates adhere to mucosal tissue.

mousse, liquid, spray, and aerosol.

5. The drug formulation of claim 4, wherein the carrier is a hydroalcoholic gel.

6. The drug formulation of claim 1 wherein the drug is selected from the group consisting of chemotherapeutic agents, hormones, hormone releasing agents, hormone analogs, and anti-proliferative agents.

7. The drug formulation of claim 6 wherein the drug is selected from the group consisting of danazol, bromocriptine, tamoxifen, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens.

8. The drug formulation of claim 6 wherein the drug is a danazol.

9. The drug formulation of claim 1 in a dosage effective to treat benign diseases of the breast.

7. The formulation of claim 1 where the micro- or nano- particulates comprise polymer altering rates of drug absorption in the region to be treated.

8. The formulation of claim 1 which can be administered vaginally, intraperitoneally, or directly on the reproductive organs of interest.

9. The formulation of claim 8 wherein the drug is danazol and wherein the formulation is suitable for vaginal administration in patients in need thereof and is in a dosage effective for treatment of endometriosis.

10. The formulation of claim 1 wherein the drug is an anticancer drug, cytotherapeutic or anti-proliferative drug in a dosage effective for treatment of cancer in the region of the patient where administered.

11. The formulation of claim 1 wherein the drug is an antiviral agent effective for treatment of viral infections selected from genital herpes and genital papilloma viral infections.

12. The formulation of claim 1 wherein the drug is an antifungal agent effective for treatment of vaginal fungal infections.

13. The formulation of claim 1 wherein the drug is an antibacterial agent effective for treatment of vaginal and endometrial bacterial infections.

14. The formulation of claim 1 wherein the drug is

	a steroid or steroid-like product suitable for treatment of endocrine conditions. 15. The formulation of claim 14 wherein the drug is effective for treatment of menopause, infertility, contraception, dysfunctional uterine bleeding, dysmenorrhea, adenomyosis, or assisted reproductive technologies. 31. A composition for treating endometriosis comprising danazole in a form promoting quick uptake into the blood stream when applied to the mucosal membranes of the female reproductive tract, wherein danazole is in a form delivering an effective amount to decrease the discomfort of endometriosis which is less than the effective amount when the drug is administered systemically. 32. The composition of claim 31 wherein the danazole is in a form selected from the group consisting of foams, tablets, and creams. 33. The composition of claim 32 wherein the danazole is in a form suitable for application to the uterus.

Independent claim 1 of Ragavan 1 defines a micro- or nano-particulate drug formulation for local or regional topical administration of an effective amount to provide relief from symptoms associated with a disease or disorder in a region in patients in need thereof, wherein the effective amount is less than the effective amount when the drug is administered

systemically. Independent claim 31 of Ragavan 1 defines a composition for treating endometriosis comprising danazol in a form promoting quick uptake into the blood stream when applied to the mucosal membranes of the female reproductive tract, wherein danazol is in a form delivering an effective amount to decrease the discomfort of endometriosis which is less than the effective amount when the drug is administered systemically.

None of claims 1-15 and 31-33 of Ragavan 1 defines a formulation comprising a drug in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue.

None of the claims define a formulation comprising a drug and a penetration enhancer to promote delivery of the drug across the stratum corneum.

There is nothing in the claims of Ragavan 1 that leads one to make a formulation of a drug in combination with a penetration enhancer as claimed.

"Region" as recited in claim 1 of Ragavan 1 is defined as reproductive organs and their surrounding environs - which include uterus, fallopian tube, peritoneal space, pelvic cul-de-sac, ovaries, perineum and the rectovaginal region (*See* Ragavan 1, at least at col. 7, lines 37-41). Thus, Ragavan 1 claims formulations for delivery across mucosal membranes. The Examiner has provided no reasons (*See* MPEP §804) why one of ordinary skill in the art would conclude that the claimed formulation (i.e. a formulation with excipients that promote delivery across the **skin**, a relatively non-permeable material), is an obvious variation of the formulations claimed in Ragavan 1 (i.e. formulations with excipients for delivery across mucosal membranes). Furthermore, there would be no motivation for one of ordinary skill in the art to modify the formulations claimed in Ragavan 1 to include a penetration enhancer as claimed.

Moreover, the dependent claims are drawn specifically to danazole, a steroidal drug, which is specifically excluded from the claimed subject matter.

In summary, the claims differ:

In drug to be delivered (preferably steroidal vs. non-steroidal)

In region to be treated (reproductive, highly vascularized mucosal site, compartmentalized via a reproductive blood barrier in women vs. skin on breasts)

Need for excipient (no excipient vs. required to have penetration enhancer – which is determined by difference in properties of region, site of application)

For treatment of different disorders (preferably endometriosis vs. diseases of breast)

Therefore, claims 1-9 are non-obvious over claims 1-15 and 31-33 of Ragavan 1.

U.S Patent No. 6,652,874 to Ragavan, et al. ("Ragavan 2")

Claims 1-9 were rejected under the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 17 of Ragavan 2. This rejection is improper based on a comparison of pending claims 1-9 with claims 1-4 and 17 of the Ragavan 2 as shown below.

Claims as Amended	**Claims of Ragavan 2**
1. A drug formulation comprising a drug in an amount effective to provide relief from diseases or disorders of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote	1. A drug formulation, comprising drug particles suitable for local or regional administration of an effective amount of the drug to provide relief from symptoms in a region in patients in need thereof, wherein the effective amount is less than the effective

delivery of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic. 2. The drug formulation of claim 1 wherein the drug is soluble in aqueous solutions. 3. The drug formulation of claim 1 wherein the drug is in the form of micro- or nano-particulates. 4. The drug formulation of claim 1 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol. 5. The drug formulation of claim 4, wherein the carrier is a hydroalcoholic gel. 6. The drug formulation of claim 1 wherein the drug is selected from the group consisting of chemotherapeutic agents, hormones, hormone releasing agents, hormone analogs, and anti-proliferative agents. 7. The drug formulation of claim 6 wherein the drug is selected from the group consisting of danazol, bromocriptine, tamoxifen, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens. 8. The drug formulation of claim 6 wherein the drug is a danazol. 9. The drug formulation of claim 1 in a dosage	amount when the drug is administered systemically and wherein the drug is selected from the group consisting of anticancer drugs, cytotherapeutic drugs, anti-proliferative drugs, and antiviral drugs. 2. The formulation of claim 1 wherein the region is the female reproductive organs. 3. The formulation of claim 2 wherein the patients have a disorder located in the reproductive organs. 4. The formulation of claim 1 wherein the drug is in the form of micro- or nano- particulates. 17. The formulation of claim 1, wherein the formulation is in a carrier promoting quick uptake of the drug into the blood stream, a carrier manipulating release of drug, or a carrier promoting adhesion of the drug, wherein the carrier is selected from the group consisting of a liquid suspension or dispersion, a hydrogel suspension or dispersion, a topical ointment, a cream, a lotion, and a foam.

effective to treat benign diseases of the breast.	

Independent claim 1 of Ragavan 2 defines a drug formulation, comprising drug particles suitable for local or regional administration of an effective amount of the drug to provide relief from symptoms in a region in patients in need thereof, wherein the effective amount is less than the effective amount when the drug is administered systemically and wherein the drug is selected from the group consisting of anticancer drugs, cytotherapeutic drugs, anti-proliferative drugs, and antiviral drugs.

The same comments and analysis apply as above.

None of claims 1-4 and 17 of Ragavan 2 defines to a formulation comprising a drug in a pharmaceutically acceptable capable of delivering the drug to the breast tissue.

None of the claims define a formulation comprising a drug and a penetration enhancer to promote delivery of the drug across the stratum corneum.

There is nothing in claims 1-4 and 17 of Ragavan 2 that leads one to make a formulation of a drug in combination with a penetration enhancer.

"Region" as recited in claim 1 of Ragavan 2 is defined as reproductive organs and their surrounding environs - which include uterus, fallopian tube, peritoneal space, pelvic cul-de-sac, ovaries, perineum and the rectovaginal region (*See* Ragavan 2, col. 6, lines 32-39). Ragavan 2 claims formulations for delivery across mucosal membranes. The Examiner has provided no reasons (*See* MPEP §804) why one of ordinary skill in the art would conclude that the claimed

formulation (i.e. a formulation with excipients that promote delivery across the skin), is an obvious variation of the formulations claimed in Ragavan 2 (i.e. formulations with excipients for delivery across mucosal membranes) when the requirements are so drastically different. Furthermore, there would be no motivation for one of ordinary skill in the art to modify the formulations claimed in Ragavan 2 to include a penetration enhancer as claimed.

Therefore, claims 1-9 are non-obvious over claims 1-4 and 17 of Ragavan 2.

U.S. Patent No. 6,416,778 to Ragavan, et al. ("Ragavan 3")

Claims 1-9 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 12 of Ragavan 3. This rejection is improper based on a comparison of pending claims 1-9 with claims 1-3 and 12 of the Ragavan 3 as shown below.

Claims as Amended	**Claims of Ragavan 3**
1. A drug formulation comprising a drug in an amount effective to provide relief from diseases or disorders of the breast in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue, comprising a penetration enhancer to promote delivery of the drug across the stratum corneum, wherein the drug is not a non-steroidal anti-inflammatory or analgesic. 2. The drug formulation of claim 1 wherein the drug is soluble in aqueous solutions.	1. A drug formulation comprising drug particles suitable for regional administration of an effective amount to provide relief from symptoms of a disease or disorder selected from the group consisting of endometriosis, endometrial bacterial infections, cancer, and endocrine conditions in a region in patients in need thereof, wherein the region is selected from the group consisting of the uterus, fallopian tubes, peritoneal space, pelvic cul-de-sac, ovaries, and urinogenital tract, wherein the

3. The drug formulation of claim 1 wherein the drug is in the form of micro- or nano-particulates. 4. The drug formulation of claim 1 wherein the carrier is selected from the group consisting of a gel, ointment, lotion, emulsion, cream, foam, mousse, liquid, spray, and aerosol. 5. The drug formulation of claim 4, wherein the carrier is a hydroalcoholic gel. 6. The drug formulation of claim 1 wherein the drug is selected from the group consisting of chemotherapeutic agents, hormones, hormone releasing agents, hormone analogs, and anti-proliferative agents. 7. The drug formulation of claim 6 wherein the drug is selected from the group consisting of danazol, bromocriptine, tamoxifen, luteinizing hormone-releasing hormone (LHRH) analogues, and antiestrogens. 8. The drug formulation of claim 6 wherein the drug is a danazol. 9. The drug formulation of claim 1 in a dosage effective to treat benign diseases of the breast.	effective amount is a dosage which results in low serum drug levels and reduced side effects as compared to systemic administration of the drug, and wherein the formulation is in a carrier promoting quick uptake of the drug into the blood stream, a carrier manipulating release of drug, or a carrier promoting adhesion of the drug selected from the group consisting of a liquid suspension or dispersion, a hydrogel suspension or dispersion, a topical ointment, a cream, a lotion, and a foam. 2. The formulation of claim 1 wherein the region is the female reproductive organs. 3. The formulation of claim 2 wherein the patients have a disorder located in the reproductive organs. 12. A composition for treating endometriosis comprising particulate danazole in a carrier promoting quick uptake of the drug into the blood stream, a carrier manipulating release of drug, or a carrier promoting adhesion of the drug, when applied to the mucosal membranes of the female reproductive tract, wherein the carrier is selected from the group consisting of a liquid suspension or dispersion, a hydrogel suspension or dispersion, a topical ointment, a

	cream, a lotion, and a foam wherein the dosage of the danazole is effective to reduce the symptoms of endometriosis without causing blood levels of danazole achieved with systemic administration of the danazole.

Independent claim 1 of Ragavan 3 defines a drug formulation comprising drug particles suitable for regional administration of an effective amount to provide relief from symptoms of a disease or disorder selected from the group consisting of endometriosis, endometrial bacterial infections, cancer, and endocrine conditions in a region in patients in need thereof,

wherein the region is selected from the group consisting of the uterus, fallopian tubes, peritoneal space, pelvic cul-de-sac, ovaries, and urinogenital tract, wherein the effective amount is a dosage which results in low serum drug levels and reduced side effects as compared to systemic administration of the drug, and

wherein the formulation is in a carrier promoting quick uptake of the drug into the blood stream, a carrier manipulating release of drug, or a carrier promoting adhesion of the drug selected from the group consisting of a liquid suspension or dispersion, a hydrogel suspension or dispersion, a topical ointment, a cream, a lotion, and a foam.

Independent claim 12 defines a composition for treating endometriosis comprising danzole and a carrier. Danazole is a STEROID, which is specifically excluded from the claims of this application.

None of claims 1-3 and 12 of Ragavan 3 defines a formulation comprising a drug in a pharmaceutically acceptable carrier capable of delivering the drug to the breast tissue.

None of the claims define a formulation comprising a drug and a penetration enhancer to promote delivery of the drug across the stratum corneum.

There is nothing in the claims of Ragavan 3 that leads one to make a formulation of a drug in combination with a penetration enhancer.

Therefore, claims 1-9 are non-obvious over claims 1-3 and 12 of Ragavan 3.

"Region" as recited in claim 1 of Ragavan 3 is defined as reproductive organs and their surrounding environs - which include uterus, fallopian tube, peritoneal space, pelvic cul-de-sac, ovaries, perineum and the rectovaginal region (*See* Ragavan 3, col. 6, lines 28-34). Thus, Ragavan 3 claims formulations for delivery across mucosal membranes. The Examiner has provided no reasons (*See* MPEP §804) why one of ordinary skill in the art would conclude that the claimed formulation (i.e. a formulation with excipients that promote delivery across the skin), is an obvious variation of the formulations claimed in Ragavan 3 (i.e. formulations with excipients for delivery across mucosal membranes). Furthermore, there would be no motivation for one of ordinary skill in the art to modify the formulations claimed in Ragavan 3 to include a penetration enhancer as claimed. Therefore, claims 1-9 are non-obvious in view of claims 1-3 and 12 of Ragavan 3.

Withdrawal of the nonstatutory double patenting rejection of claims 1-9 is respectfully solicited.

Other Amendments to the Claims

Claim 14 has been amended to correct a typographical error. Withdrawn claim 10 has been amended to recite all of the limitations of claim 1, to specify that the drug formulation is administered to the breast or chest of the patient, and that the drug is in a pharmaceutically acceptable carrier for topical administration to the breast. Claim 10 has also been amended to specify that the formulation contains a penetration enhancer. Support for this amendment can be found in the specification at least at page 5, lines 20-26, page 6, lines 28-29 and original claim 1.

Allowance of claims 1-19, as amended, is respectfully solicited.

Respectfully submitted,

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